

U.S. Serial No. 09/888,920
Amendment to Office Action dated May 26, 2004

Remarks

Claims 27 and 35 have been amended and new claims 41-45 have been added. Claims 30-34 and 40 remain withdrawn. Support for the amendments and new claims can be found in the specification, claims, and drawings as originally filed. No new matter has been added.

Claim Objection

Claim 39 is objected to for reciting "PEBA" using capital letters. The Examiner suggests using small letters because the term is not a trademark. Applicants respectfully submit that PEBA in capital letters is the conventional abbreviation used in the art for polyether block amide polymer, and the use of small letters for the abbreviation may cause confusion. The art-recognized use of PEBA in capital letters is evidenced by its use in the claims of the following recently issued US patents: 6,745,987, 6,740,507, 6,725,634, 6,685,720, 6,681,777, 6,669,060, 6,592,568, 6,581,808, and 6,566,484. Applicants submit that, while not designating a trademark, the use of capital letters for the PEBA abbreviation is recognized in the art and is thus proper for use in the claims.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 29 and 35 are rejected as failing to comply with the written description requirement because the application as filed does not contain a description for a helical wall thickness that decreases distally. Applicants respectfully traverse the rejection.

Fig. 3 as originally filed clearly shows the thickness of wall 111 decreasing from the proximal end 108 toward the distal end 110 of the strain relief 106. As the figures originally filed are considered part of the application, the elements of claims 29 and 35 were described in the application as originally filed. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. § 102 (b)

Claims 27 and 28 are rejected as being anticipated by Davila (US 5,466,230). Davila is cited as disclosing a catheter tube hub having a lumen, proximal and distal

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portions, a helical wall with bends separated by spaces, where the proximal portion of the hub is thicker than the distal portion. Applicants traverse the rejection.

Davila teach a catheter sheath introducer in which a spring is placed over the proximal end of a sheath and both are placed into a mold so the hub is formed around the sheath and spring; forming an integral unit in which a lumen is formed through the hub and sheath. See column 3, lines 17-19 and 46-59. Davila specifically teach the sheath 12 "joined to the internal body of the hub 14", the spring 15 "wound about sheath 12" and "sheath 12 and a spring 15 connected together with spring 15 embedded in the plastic of hub 14." See column 3, lines 17-19 and 58-59. In the device of Davila, the "lumen" extending through the hub is the tubular sheath 12. The instant claims recite a device in which a helical wall defines the lumen, and a plurality of bends in the helical wall are separated by spaces that extend into the passage. This is clearly shown in Figure 3 of the instant application. In the device of Davila, the spaces between the spring coils only extend to the surface of the sheath. Because the sheath defines the lumen extending through the hub, the spaces between the spring coils do not extend into the lumen.

Even if one were to consider the space under the spring coils and over the sheath as a "lumen", the device of Davila differs significantly from the claimed device. The instant claims recite the lumen extending through the hub as well as the strain relief. Any space under the spring coils and over the sheath in the device of Davila does not appear to extend into the hub because the spring and sheath are embedded in the plastic forming the hub. Any such space would thus only extend from the distal end of the hub under the spring.

Davila describes, at column 3, lines 46-59, the manufacturing process for his device as involving placing the spring 15 near the proximal end of the sheath 12 and placing part of the spring 15 and sheath 12 inside a mold cavity, and then injecting plastic into the mold to form the hub 14, such that the spring 15 and sheath 12 are embedded in the hub 14. There does not appear to be a stage during the production process when spaces between the spring coils extend into a passage for receiving a catheter tube, as is recited in independent claim 27. The lumen configured to receive a catheter tube in the device of Davila is defined by the sheath 12, and is not defined by a helical wall, as is recited in the instant claims. The spring in Davila's device is embedded in the plastic of

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the hub and wound about the sheath. Thus, the spaces between the bends in the spring do not and cannot extend into the lumen for receiving a catheter tube. Davila thus fails to teach the elements of claims 27 and 28. Withdrawal of the rejection is respectfully requested. Additionally, Davila fails to teach the elements of new claims 41-45 for at least the reasons set forth above.

Claims 27 and 28 are rejected as being anticipated by Suzuki et al. (US 4,682,981). Suzuki et al. is cited as disclosing a catheter tube hub having a lumen, proximal and distal portions, and a helical wall having bends separated by spaces, where the proximal portion is thicker than the distal portion. Applicants respectfully traverse the rejection.

Suzuki et al. teach a device including "a sheath 5 having its proximal portion fixed and supported by the hub 4." Suzuki et al. also teach "hub 4 and the sheath 5 have a through path 19 for receiving a tube 7." See column 2, lines 31-35 and FIG. 2. Suzuki et al. further teach a bending spring 23 on the sheath 5. See column 3, line 47 and FIG. 8B. In the device of Suzuki et al., the sheath 5 is fixed to the hub 4, and the spring 23 is wound around the sheath. Suzuki et al. teach that the hub and sheath have a through path for receiving a tube (column 2, lines 32-35). The lumen configured to receive a catheter tube in the Suzuki et al. device is through the sheath, not the spring. Suzuki et al. thus fail to teach a catheter tube hub in which a helical wall defines a lumen for receiving a catheter tube, and in which spaces between helical bends of the wall extend into the lumen, as is recited in the claims. Because Suzuki et al. teach the sheath being fixed to the hub, with the spring around the sheath; there are no spaces between the spring coils 23 that extend into the tube passage 19. Suzuki et al. thus fail to teach the elements of claims 27 and 28. Withdrawal of the rejection is respectfully requested. Additionally, Suzuki et al. fail to teach the elements of new claims 41-45 for at least the reasons set forth above.

Rejection under 35 U.S.C. § 103

Claims 29 and 35 are rejected as being unpatentable over Davila or Suzuki et al. as applied to claim 27, and further in view of Lalikos (US 5,143,409). As stated above, Davila and Suzuki et al. fail to teach the basic features of the invention. Lalikos does not

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supply what Davila and Suzuki et al. lack. Thus, even if the disclosures of Davila or Suzuki et al. and Lalikos were combined, one would not achieve the instantly claimed invention. Withdrawal of the rejection is respectfully requested.

Claims 36-39 are rejected as being unpatentable over Davila or Suzuki et al. as applied to claim 27, and further in view of Prichard (US 5,380,301). As stated above, Davila and Suzuki et al. fail to teach the basic features of the invention. Prichard does not supply what Davila and Suzuki et al. lack. Thus, even if the disclosures of Davila or Suzuki et al. and Prichard were combined, one would not achieve the instantly claimed invention. Withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. Any inquiry regarding this matter may be directed to the undersigned representative at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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Nov. 24, 2004


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